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45488 7590 12/12/2007
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| EXAMINER |
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TSAY, MARSHA M

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| ART UNIT | PAPER NUMBER |
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1656

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12/12/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

**Advisory Action
Before the Filing of an Appeal Brief**

Application No.

10/812,268

Applicant(s)

MOEHLENBRUCK ET AL.

Examiner

Marsha M. Tsay

Art Unit

1656

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 19 November 2007 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 6 months from the mailing date of the final rejection.
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
(a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
(b) ☐ They raise the issue of new matter (see NOTE below);
(c) ☒ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
The status of the claim(s) is (or will be) as follows:
Claim(s) allowed: _____.
Claim(s) objected to: _____.
Claim(s) rejected: 82-102 and 125.
Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:
See Continuation Sheet.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). _____.
13. ☐ Other: _____.

Continuation of 11. does NOT place the application in condition for allowance because: Claims 82-88, 91-102, 125 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Mechanic (US 5854397) in view of Gan et al. (US 5964807) as noted in the final office action.

In their after final remarks, Applicants assert Mechanic does not teach nucleus pulposus tissue and that Gail et al. fail to remedy this deficiency by teaching away from the use of donor nucleus pulposus tissue. Applicants further assert that although Gan et al. note that "tissue may be extracted from the nucleus pulposus of lumbar discs, sacral discs and cervical discs," that tissue is subsequently discarded to obtain isolated nucleus pulposus cells. According to Applicants, the isolated cells are then combined with materials intended to substitute for the discarded nucleus pulposus tissue from which they were isolated. Applicants further assert that throughout the specification, Gan et al. repeatedly emphasizes the mechanical and chemical destruction of the nucleus pulposus tissue to liberate cells for use in creating a hybrid matrix. Applicants' arguments have been fully considered but are not deemed persuasive.

The instant invention is essentially drawn to a method of intervertebral disc implant comprising 1) obtaining donor nucleus pulposus tissue, and 2) cross-linking at least a portion of the nucleus pulposus tissue. It should first be noted that "tissue" as defined in the art is an association of cells bound together by cell walls (plants) or extracellular matrix (animals) that performs particular functions. Therefore, cells are components of tissues. Gan et al. disclose a material that is prepared by combining isolated intervertebral disc cells with a biodegradable matrix, for implantation into the intervertebral disc space (col. 5 lines 15-20). Gan et al. further discloses that the intervertebral disc cell growth is guided and/or stimulated and intervertebral disc tissue is reformed (col. 5 lines 19-22). Gan et al. disclose the intervertebral disc cells are nucleus pulposus cells obtained from donor nucleus pulposus tissue (col. 8 lines 1-7) and can be cultured together with the biodegradable substrate (col. 8 lines 58-61). Therefore, it would be reasonable for one of ordinary skill to recognize that the nucleus pulposus cells will generate into nucleus pulposus tissue and combined with the biodegradable substrate to manufacture an intervertebral disc plant. As disclosed by Gan et al., nucleus pulposus contains collagen fibrils (col. 1 line 37). Mechanic discloses a process for cross-linking collagenous material, including collagen fibrils and tissues containing said fibrils (col. 4 lines 15-90), therefore, one of ordinary skill would be motivated to substitute the nucleus pulposus implant of Gan et al. into the process of cross-linking collagenous material of Mechanic because cross-linking said implant would result in a more stable bio-product that resists in vivo degradation and calcification upon implantation.

Claims 89-90 remained rejected under 35 U.S.C. 103(a) as being unpatentable over Mechanic in view of Gan et al. in view of Moore et al.

The reasons for maintaining the rejection based on Gan et al. are the same as noted above.

R. Monshipouri
MARYAM MONSHIPOURI, PH.D.
PRIMARY EXAMINER